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Safety and Economic Aspects of Ureteroscopy

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Safety and Economic Aspects of Ureteroscopy

Introduction:

Ureteroscopy (URS) is one of the most widespread endourological procedures for the treatment of urinary stones and other diagnostic purposes. Despite its minimal invasiveness, there are still numerous safety matters influencing the intraoperative and postoperative course of URS. The act of stone extraction constitutes, together with lithotripsy issues (excessive intrarenal temperature) and intraoperative irrigation problems (excessive intrarenal pressure), one of the main causes of intraoperative trauma, resulting in postoperative complications.

Further development of the URS technique and introduction of flexible instruments eliminated the natural anatomical burden present during traditional semirigid ureteroscopy (sURS). Flexible ureteroscopy (fURS) has enabled a retrograde endourological approach in cases reserved so far either for percutaneous nephrolithotomy (PNL) or shockwave lithotripsy (SWL). It resulted in the increase of stone-free rates (SFRs) after fURS; however, new logistic and economic aspects associated with service and damage of reusable flexible ureteroscopes has become an important issue. A new concept of single-use devices (e.g. LithoVue™) has been introduced on the market, in order to eliminate the significant costs of flexible ureteroscope repairs.

Our main goal was to investigate the costs of conventional reusable fURS and identify new risk factors for flexible ureteroscope damage and complicated postoperative courses, as well as provide solutions increasing the intraoperative safety of patients during URS procedures.

The project has been approved by bioethical committee of University of Lübeck (Decision No. 18-251).

Study (1):

Publication:

Ozimek T, Schneider MH, Hupe MC, Wiessmeyer JR, Cordes J, Chlosta PL, Merseburger AS, Kramer MW (2017) Retrospective Cost Analysis of a Single-Center Reusable Flexible Ureterorenoscopy Program: A Comparative Cost Simulation of Disposable fURS as an Alternative. J Endourol 31(12):1226-1230
Impact Factor 2.038

Aims & Methods:

The goal of the presented study was to retrospectively analyze the economic aspect of the application of reusable fURS in a single-center setting, to simulate the comparison of the actual expenses with the potential costs of single-use scopes (e.g. LithoVue™) based on the price offered by the manufacturer, as well as to perform a case analysis of damaged flexible ureteroscope to determine the potential risk factors for reusable flexible scope defect.
All fURS cases performed at the Department of Urology, University Hospital Schleswig-Holstein, Luebeck, Germany between January 2013 and December 2016 have been retrospectively analyzed. fURS procedures in the years 2013–2015

were performed exclusively with seven reusable Karl Storz Flex-X2 scopes. Our real costs consisted of the price for three new flexible scopes (Olympus URF-V), which have been in service from the beginning of 2016, and the repair costs, as well as the reprocessing cost defined as the cost of labor of trained hospital workers and the flat rate sterilization fee of €123 per case (contract with external company - Vanguard AG). The labor cost amounted to €20 per case. After the surgery, reusable scopes were cleaned, tested for leaks, disinfected with 30 ml of 1% GIGASEPT PAA (Schülke & Mayr GmbH), dried and prepared for transport for external sterilization. The aforementioned process took around one hour and was carried out by a trained employee.

The repairs of defective fURS devices were associated with additional costs and conducted by an external outsourced company (Drägerwerk AG & Co. KGaA). The flexible scopes that were deemed defective during routine postoperative processing were exchanged for new devices by the manufacturer. The purchase of seven Karl Storz Flex-X2 scopes that had been acquired before 2013 were not considered for the analysis. The real costs and the average cost per procedure were compared with the anticipated cost of the equivalent number of single-use scopes (e.g. LithoVue™) procedures.

Moreover, we performed a case analysis of damaged flexible scopes to recognize factors that could be considered as risk factors for reusable flexible scope defects. The infundibulopelvic angle (IPA) was measured in accordance with the El-Bahnasy definition. The angle was measured between the ureteropelvic axis and central axis of the lower infundibular pole based on retrograde pyelography (RPG) images.

Results:

During the investigated period (January 2013 to December 2016), 423 (100%) fURS procedures were conducted, 102 (24.11%) for diagnostic purposes and 321 (75.89%) for kidney stone therapy. The latter subgroup consisted of 148 (34.99%) fURS procedures for simple stone extraction and 173 (40.9%) procedures for stone extraction combined with laser (Ho:YAG) lithotripsy via fURS.

In 32 out of 423 (7.57%) fURS cases, the scopes were postoperatively deemed defective and required repair. Of these, nine had been used for diagnostic fURS (9/102 cases; 8.82%), seven for fURS with stone extraction (7/148 cases; 4.73%) and 16 for fURS with stone extraction and laser (Ho:YAG) lithotripsy via fURS (16/173 cases; 9.25%). Thirty-one out of 32 (96.86%) cases with proven flexible ureteroscope defect involved exploration of the lower kidney pole. Twenty out of 23 (86.96%) cases with stone retrieval included stones situated in the lower calyces. The stones that were extracted with subsequent fURS device damage had a mean diameter of 8 mm (SD ±6.67 mm) and a mean density of 918 HU (SD ±292 HU). The mean OR time for cases with fURS device damage was 80 min (SD ±32 min). More than half of the defective fURS cases (18/32 cases; 56.25%) were characterized by a steep IPA (≤50°) measured in intraoperative RPG. Postinterventional stone-free status was obtained in less than half of cases (10/23 cases; 43.48%). External repair reports revealed two main causes of fURS device damage: device leakiness (18/32 cases; 56.25%) and tip break-off (7/32 cases; 21.86%). The average number of cases resulting in fURS device damage was estimated to be 14.4. Detailed results are presented in Tables 1 and 2.

The total cost of all 423 fURS procedures was €212,880.02. The average cost per fURS procedure was estimated to be €503.26. A detailed summary of the costs is presented in Table 3. The assumed price per single-use LithoVue™ scope was €1000.

Table 1. Damaged flexible ureteroscopes - Preoperative Characteristics.

Number of Patients	32
fURS Indication	
Diagnostic	9/32 (28.13%)
Kidney stone	23/32 (71.87%)
Recurrent Urolithiasis Patients	14/23 (60.87%)
Recent Urolithiasis Procedures	
SWL	5/23 (21.74%)
URS	5/23 (21.74%)
PNL	2/23 (8.69%)
Stone characteristics	
Single stone	9/23 (39.13%)
Multiple stones	14/23 (60.87%)
Stone diameter	8 (SD±6.67)
<10 mm	12/23 (52.17%)
10-20 mm	8/23 (34.78%)
>20 mm	3/23 (13.04%)
Stone density (HU)	918 (SD±292)
Stone location	
Lower pole	20/23 (86.96%)
Upper pole	1/23 (4.35%)
Renal Pelvis	2/23 (8.69%)

Table 2. Damaged flexible ureteroscopes - Intraoperative Characteristics.

OR Time	80 min (SD±32 min)
Laser (Ho:YAG) Application	
via fURS	16/32 (50%)
Median Total Laser Energy (kJ)	
via fURS	1,2
Lower Pole Inspection	31/32 (96.88%)
Infundibulopelvic Angle (retrograde Pyelography)	
≤50°	18/32 (56.25%)
>50°	10/32 (31.25%)
no data	4/32 (12.5%)
Stone-free rate	10/23 (43.48%)
Repair reports	
Leakiness	18/32 (56.25%)
Tip break-off	7/32 (21.86%)
Other cause	7/32 (21.86%)

Table 3. Costs of reusable fURS program 2013-2016.

	Diagnostic fURS	fURS for kidney stones	Per Case
fURS Cases	102	321	
Repairs	€24’534.54	€77’654.48	€241.58
Reprocessing	€14’586.00	€45’903.00	€143.00
New Devices	€50’202.00		€118.68
Total Cost	€212’880.02		€503.26

Conclusions:

The shift from reusable fURS to single-use fURS only seems to be a costlier option for high volume centers. Despite any possible inaccuracies of our analysis, we have shown that the cost imbalance between single-use (€1000 per LithoVue™) and reusable (€503.26 per case) fURS is significant. Our reusable fURS program seems to be more cost-efficient, despite some of the advantages of single-use LithoVue™, such as better vision and maneuverability, best possible brand-new device availability and a reduced risk of infection transmission. Single-use fURS could be a feasible solution for endourological treatment in developing countries, where the resources necessary for service and maintenance of reusable scopes are scarce.

The management of multiple, large stones in the lower kidney calyces of recurrent stone-formers with laser lithotripsy, as well as a steep IPA, seem to be the relevant risk factors for fURS defect. For these cases in particular, single-use fURS may be a cost-effective alternative. A better comprehension of the damage mechanisms is a key for a proper indication to use the more expensive disposable ureteroscopes. Prospective comparative studies in regard to economic differences between disposable and reusable fURS, together with confirmation of the proposed damage risk factors, is warranted.

Study (2):

Publication:

Ozimek T, Cordes J, Wiessmeyer JR, Schneider MH, Hupe MC, Gilbert N, Merseburger AS, Kramer MW (2018) Steep Infundibulopelvic Angle (IPA) as a New Risk Factor for Flexible Ureteroscope Damage and Complicated Postoperative Course. J Endourol 32(7):597-602
Impact Factor 2.038

Aims & Methods:

The recognition of risk factors of reusable flexible ureteroscope defect would be favorable in terms of determining indications for single-use fURS, in order to reduce the proportion of reusable flexible ureteroscope damage. Our own data and experience imply that excessive flexion of the tip of the flexible device to overcome a steep IPA and explore the lower kidney pole could be an important element of fURS device damage mechanism.

The goal of the presented study was to investigate the role of IPA as a risk factor of reusable flexible ureteroscope damage. The relation of IPA to other intraoperative and postoperative factors, such as complication rate, fluoroscopy time and length of hospital stay (LOS), has also been analyzed.

A retrospective monocentric study was performed on 381 fURS procedures conducted between September 2013 and March 2017 at the Department of Urology, University Hospital Schleswig-Holstein, Luebeck, Germany. Written patient consent was obtained at least 24 hours preoperatively. No routine preoperative or intraoperative antibiotic prophylaxis was applied. A preoperative antibiotic course was warranted only in patients with positive preoperative urine culture. All patients were operated on under general anesthesia in the supine lithotomy position. All procedures were carried out with modern reusable flexible ureteroscopes: Karl Storz Flex-X2 and Olympus URF-V. fURS was usually preceded by sURS.

The IPA was retrospectively digitally measured (Agfa HealthCare IMPAX Software) in accordance with the El-Bahnasy definition and based on recorded intraoperative RPG images. The angle was determined between the ureteropelvic axis and central axis of the lower pole infundibulum.

Contrast (Urolux Retro®, CS Diagnostics GmbH) was applied into the proximal ureter through the semirigid ureteroscope, prior to the use of the fURS device. Laser lithotripsy of the stones was performed with SlimLine 200 μm Fiber (Boston Scientific) and Holmium Laser (Lumenis VersaPulse® PowerSuite™ 100 W). Uromed Stonizer® tipless (1.9F) or NGage® (2.2F) nitinol baskets were applied for kidney stone retrieval with flexible scope. Tissue samples were gathered whenever indicated with Olympus FB 56D-1 (1.2mm) or Karl Storz (3.0F) biopsy forceps. Exploration of all calyces, including the lower kidney pole, is the state of the art for every fURS procedure performed in our department. Ureteral double-J stent reinsertion was not performed routinely but was dependent on the complexity level of the surgery and the extent of postoperative ureteral lesions. Details regarding postoperative cleaning and processing of reusable flexible scopes have been already described in Study (1).

Stone-free status was, in the majority of the cases, determined intraoperatively by the endourologist. Radiological postoperative reevaluation with computer tomography (CT) or kidney, ureter, and bladder (KUB) radiography was not a standard and was indicated only in cases of uncertainty regarding postoperative stone-free status or before second look procedures.

Investigated parameters were SFRs, fURS device defects, intraoperative and postoperative complications, LOS, operation and fluoroscopy time, recurrent stone former status and presence of lower pole kidney stones.

A recurrent stone former was defined as a patient with at least one stone episode in the past. Flexible ureteroscopes were declared defective during routine postoperative processing. The Clavien-Dindo scale was applied to classify the intraoperative and postoperative complications. A routine hospital stay amounted to 48 postoperative hours and was dependent on the German reimbursement system.

Statistical testing was conducted by RStudio (Version 1.0.136) software. Mean value with standard deviation (SD) for normally distributed variables and median value with minimum and maximum values for variables without normal distribution, as well as percent values for categorical variables were applied for descriptive statistics. The Shapiro-Wilk test was used for normal distribution testing. Depending on its results, univariate analysis was done with the unpaired t-test or Mann-Whitney U (MWU) or Pearson correlation test. The level of significance was defined as $p<0.05$.

Results:

To sum up, 381 fURS procedures were conducted between September 2013 and March 2017: 260 (68.24%) for kidney stone surgery and 121 (31.76%) for diagnostic purposes. Selected preoperative characteristics are presented in Table 4. The majority of therapeutic fURS procedures involved stones of the lower calyx (194/260 cases; 74.62%) and stones smaller than 2 cm (254/260 cases; 97.69%). Flexible ureteroscopes were postoperatively deemed defective in 38 (9.97%) cases. Lower pole kidney stones were managed in 23 out of 38 fURS (60.53%) cases with device damage.

Two major causes of the recorded defects were ureteroscope leakage (23/38 cases; 60.53%) and defects of the Bowden cable system (7/38 cases; 18.42%).

Median IPA in the analyzed cohort was 54°. Extended postoperative hospital stay (over 2 days) was reported in 56 (14.93%) cases. Intraoperative and postoperative characteristics are shown in Table 5.

Relevant complications requiring additional pharmacological therapy (Clavien-Dindo ≥2) were observed in 39 (10.24%) patients. Postoperative urinary tract infections requiring antibiotic therapy (Clavien-Dindo Grade 2, 27/39 cases; 69.23%) constituted the majority of recorded complications (Table 6). In one case DJ reinsertion (Clavien-Dindo Grade 3b) and in two cases intensive therapy (Clavien-Dindo Grade 4) were needed as a part of postoperative sepsis management. Mortality was limited to one case of postoperative pneumonia.

In univariate analysis, damaged fURS devices correlated with significantly steeper IPA values (Median 42.5° vs. 56.0°, $p<0.001$).

Almost all recorded fURS defects happened when the IPA was 60° or less (33/38 cases; 86.84%). Moreover, postoperative flexible device defect followed one out of four cases with an IPA smaller than or equal to 35° (17/61 cases; 27.87%).

Steep IPA was also significantly associated with the prevalence of Clavien-Dindo ≥2 complications (Median 51.0° vs. 55.0°, $p=0.005$) and an extended hospital stay (Median 51.0° vs. 55.0°, $p=0.014$). Figure 1 depicts boxplots of these significant parameters. No influence of IPA on SFR or operation time was observed ($p>0.05$, Table 7).

The linear model did not confirm any relevant correlation between IPA and operating time (Pearson r = 0.036, p=0.486) or between IPA and fluoroscopy time (Pearson r = 0.022, p=0.672).

Table 4. Preoperative characteristics. Percentages and standard deviations for mean values in brackets.

Number of Cases	381
fURS Indication	
Diagnostic	121/381 (31.76%)
Kidney stone disease	260/381 (68.24%)
Kidney stone characteristics	
Single stone	125/260 (48.08%)
Multiple stones	135/260 (51.92%)
Mean maximal stone diameter (mm)	7.11 (SD±4.27)
<10 mm	199/260 (77.61%)
10-20 mm	55/260 (21.15%)
>20 mm	2/260 (0.77%)
no data	4/260 (1.54%)
Mean Stone density (HU)	846.31 (SD±314.37)
Kidney Stone location	
Lower Calyx	194/260 (74.62%)
Singular Lower Calyx Stone	76/260 (29.23%)
Middle Calyx	67/260 (25.77%)
Upper Calyx	39/260 (15.00%)
Renal Pelvis	39/260 (15.00%)
Ureteral Stone	105/381 (27.56%)

Table 5. Intraoperative and postoperative characteristics. Percentages, standard deviations for mean values and minimum/maximum for median values in brackets.

Mean Operation time	73.23 (SD±36.31)
≥ 60 min	209/381 (54.86%)
≥ 90 min	115/381 (30.18%)
no data	11/381 (2.89%)
Holmium laser application	175/381 (45.93%)
via fURS	110/381 (28.87%)
Median fluoroscopy time (s)	70 (8; 920)
Biopsy	32/381 (8.40%)
via fURS	24/381 (6.30%)
Median RPG Infundibulopelvic Angle (degrees)	54.0 (7.0; 122.0)
Stone-free rate (overall for kidney stones)	191/260 (73.46%)
Lower pole stones	138/194 (71.13%)
Singular lower pole stones	59/76 (77.63%)
Length of postoperative hospital stay[a]	
> 2 days	56/375 (14.93%)
no data	2/375 (0.53%)
Clavien Dindo ≥ 2	39/381 (10.24%)
Flexible ureteroscope defect	38/381 (9.97%)
Diagnostic fURS	9/121 (7.44%)
Kidney Stone fURS	29/260 (11.15%)

[a] 6 cases excluded – consecutive surgery (e.g. Nephrectomy) during the same hospital stay.

Table 6. Intraoperative and postoperative complications.

Complication	Clavien Dindo Grade	No. of Patients
Bleeding complications	1	12/381 (3.15%)
	2	4/381 (1.05%)
Urinary tract infection	2	24/381 (6.30%)
	3b	1/381 (0.26%)
	4	2/381 (0.52%)
Perforation of the upper urinary tract	2	5/381 (1.31%)
Pneumonia	4	1/381 (0.26%)
	5	1/381 (0.26%)
No data		2/381 (0.52%)

Figure 1. Boxplots of statistically significant parameters (p<0.05).

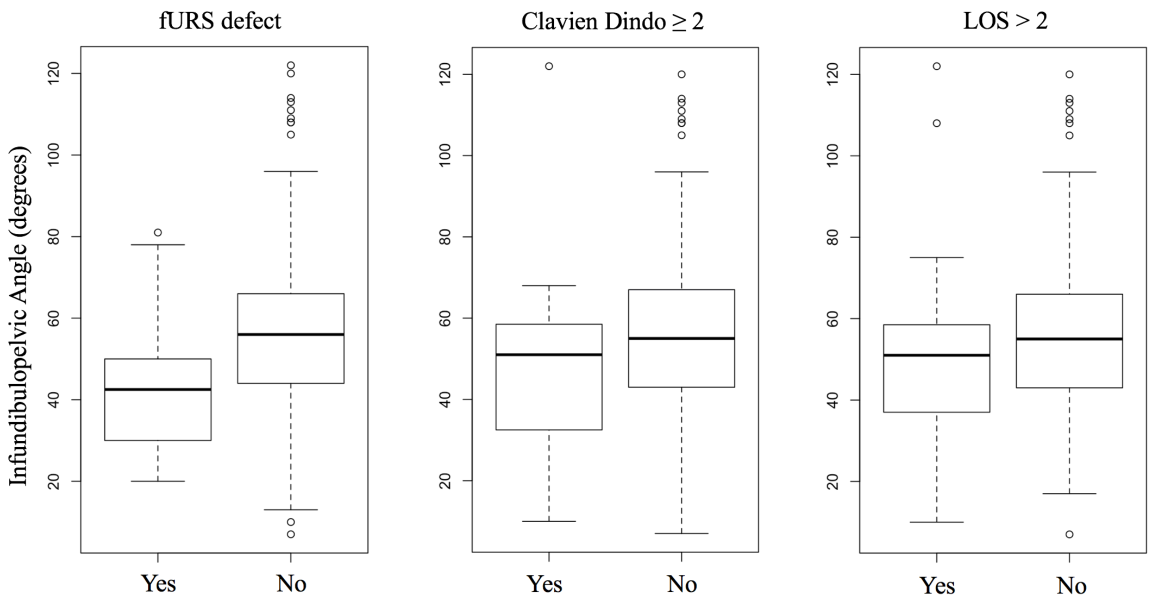

Table 7. Univariate statistical analysis with median values of infundibulopelvic angle. Minimal and maximal values in brackets.

	Yes	No	p-Value**
fURS defect	42.5 (20.0; 81.0)	56.0 (7.0; 122.0)	<0.001
Clavien Dindo ≥ 2	51.0 (10.0; 122.0)	55.0 (7.0; 120.0)	0.005
LOS > 2 days	51.0 (10.0; 122.0)	55.0 (7.0; 120.0)	0.014
Operation time ≥ 60 min	56.0 (10.0; 120.0)	53.5 (7.0; 122.0)	0.172
Operation time ≥ 90 min	56.0 (23.0; 120.0)	54.0 (7.0; 122.0)	0.604
Stone free (overall for kidney stones)	55.0 (19.0; 120.0)	52.5 (7.0; 95.0)	0.214
Stone free (lower pole stones only)	53.85* (SD±17.49)	52.57* (SD±18.30)	0.654***
Recurrent stone former	54.0 (10.0; 105.0)	55.5 (7.0; 122.0)	0.081
Lower pole stone presence	53.0 (7.0; 113.0)	57.0 (10.0; 120.0)	0.438

* mean value

** MWU= Mann-Whitney U-test

*** t-test

Conclusions:

We reveal for the first time results depicting a relevant relation between the anatomy of the calyceal system and the defect rate of reusable flexible ureteroscopes.

Our study implies that steep IPA, regardless of the complexity of the stone extraction, has an impact on the endurance of reusable fURS devices. Moreover, we observed that, some damage occurred not only in stone therapy procedures (29/260 cases; 11.15%) but also in diagnostic procedures (9/121 cases; 7.44%). Thereby, it is likely that IPA plays part in ureteroscope damage not only in typical cases with stones of the lower calyx. Furthermore, steep IPA was linked to an extended hospital stay and the occurrence of intraoperative and postoperative complications (Clavien-Dindo ≥2). Therefore, patients with steep IPA require not only cautious operative performance by the endourologist but also additional care during the postoperative period.

Based on our results, extra intraoperative and postoperative caution in patients with a steep IPA of 60° or less is recommended. Further investigation of damage mechanisms is vital for the correct indication to use expensive single-use ureteroscopes. The importance of IPA as a risk factor has to be validated in prospective trials.

Study (3):

Publication:

Cordes J, Nguyen F, Pinkowski W, Merseburger AS, Ozimek T (2018) A New Automatically Fixating Stone Basket (2.5 F) Prototype with a Nitinol Spring for Accurate Ureteroscopic Stone Size Measurement. Adv Ther 35(9):1420-1425
Impact Factor 3.085

Aims & Methods:

Ureteroscopy (URS) is, according to European Association of Urology (EAU) Guidelines, the therapy of choice for ureteral stones and kidney stones of diameter smaller than 2 cm. The increasing global prevalence of kidney stone disease and the advantageous features of URS (i.e. low invasiveness, high SFRs, and relatively low risk of intraoperative and postoperative complications) allow us to forecast a growing demand for URS in the future.

Low-dose noncontrast computer tomography (CT) is the diagnostic standard for acute flank pain and, thereby, for planning of further stone treatment. Nevertheless, the precision of CT-oriented preoperative stone-size measurement, especially regarding ureteral stones, may be inexact. Furthermore, Patel et. al. showed that the CT-based assessment of stone diameter for larger stones (≥4 mm) may be less accurate than intraoperative estimation by the endourologist. Therefore, a supplementary credible stone-size measuring tool during URS would be helpful for deciding whether to carry out direct stone retrieval or laser lithotripsy for larger stones.

Our study group already introduced a nonlinear millimeter scale coupled with various self-closing nitinol stone baskets (2.5, 3.0, and 4.0 F) to optimize intraoperative stone-size measurements. The 2.5 F nitinol basket was the most precise for measuring stones of diameter greater than 6 mm with sensitivity of 56% and specificity of 84%. The previous study of our working group revealed that the cognitive visual ureteroscopic assessment was more accurate than the basket measurement. The basket system could have been inferior to visual measurement due to a material mismatch between the steel spring and the nitinol basket, which may have affected the precision of the measurement. This phenomenon could be explained by different material-specific relationships of steel and nitinol regarding their stress and strain abilities. At the beginning, steel is not flexible and presents increasing stress during engagement of the stone, whereas nitinol shows more strain and less stress. Even less stress is measured during the reverse action of stone disengagement. Therefore, to eliminate the described mismatch and to enhance the measurement precision, a new tipped basket prototype, particularly for ureteral and renal pelvic stones, has been proposed in which the steel spring has been replaced with a nitinol spring.

Results:

The tipped automatically fixating stone basket was composed of nitinol to ensure safety to the adjacent urothelial tissue and best possible performance. A suitable nitinol spring replaced the steel spring as a part of the stone-fixating mechanism.

The slider on the front side of the handle opens the basket and enables the stone to be grasped. The handle possesses two unique design features: firstly, it has an aforementioned spring mechanism that provides automatic stone fixation in the basket, and secondly, it is equipped with a disconnectable and reconnectable handle so that the ureteroscope can be entirely withdrawn, whereas the basket with the engaged stone remains in place. The handle can be reconnected on demand.

The measuring scale spreads from 2 mm (green) through 5 mm (yellow) to 8 mm (red). The scale is nonlinear due to the nonlinear dependence between the actual stone diameter and the distance marked on the scale. The newly proposed prototype eliminates the material discrepancy between the basket and the spring, which was present in the former prototype.

Conclusions:

Based on the available literature, endourologists are capable of assessing residual stone size precisely enough to intraoperatively decide about direct retrieval or further laser lithotripsy. On the other hand, our study group already proved that it was viable to measure the stone with the mentioned basket handle scale, which could be especially handy for junior endourologists; however, improvements regarding the precision of this new method were necessary and a possible solution has been proposed in this current study. The new automatically fixating stone basket with a nitinol spring has the potential to enhance the safety and efficiency of endourological stone retrieval; however, further validation of the described prototype regarding measurement accuracy, durability of the device and patient safety is needed.

Sicherheit und ökonomische Aspekte der Ureterorenoskopie

Alle der unten genannten Publikationen sind in den ersten drei Jahren meiner assistenzärztlichen Tätigkeit in der Klinik für Urologie des Universitätsklinikums Schleswig-Holstein (Campus Lübeck) entstanden. Sie adressieren aktuelle Fragestellungen der Ureterorenoskopie als eines der am häufigsten angewandten endoskopischen Verfahren zur Steintherapie und Diagnostik des oberen Harntraktes. Die unten genannten Publikationen sind in einer logischen und zeitlichen Reihenfolge entstanden, hochrangig und peer-reviewed publiziert und als Ausdruck einer sorgfältigen und detaillierten Auseinandersetzung mit diesem Themenkomplex zu betrachten. Das Forschungsvorhaben wurde bei der Ethikkomission der Universität zu Lübeck angezeigt und genehmigt (Aktenzeichen 18-251).

Die erste Publikation (Erstautorenschaft) setzt sich mit der Kostenanalyse der konventionellen flexiblen Ureterorenoskopie (fURS) sowie Ursachenanalyse für Defekte von wiederverwendbaren flexiblen Ureterorenoskopen auseinander. Die Verwendung der fURS ist aufgrund Anschaffung, Wartung, Sterilisation und in Bezug auf die Reparaturanfälligkeit kostenintensiv. Die Verwendung von Einmalgeräten bietet demgegenüber eine interessante Alternative, wobei aktuelle Studien die generelle Verwendung als nicht rentabel eingestuft hatten. Ziel der Arbeit war es, über eine dezidierte retrospektive Kostenanalyse wiederverwendbarer fURS-Geräte die Grundlage für die mögliche Anschaffung von Einmalgeräten unter Berücksichtigung von Risikofaktoren für fURS Defekte zu schaffen. Unsere Untersuchung zeigte, dass die endoskopische Behandlung von

Steinen, besonders der unteren Kelchgruppe sowie der kombinierte Lasereinsatz die Defektanfälligkeit von flexiblen URS-Geräten erhöht. Selbst die diagnostische fURS scheint mit einem Defektrisiko einherzugehen. Zusammenfassend konnte in der Kostensimulation festgestellt werden, dass die Fortsetzung der wiederverwendbaren Ureterorenoskopie deutlich kosteneffizienter zu sein scheint gegenüber der Verwendung von Einmalgeräte unter Berücksichtigung der derzeit angebotenen Preise. Diese liegen zurzeit zwischen 800-1000 € pro Einsatz.

In der zweiten Publikation (Erstautorenschaft) wird die bereits in der ersten Arbeit avisierte Bedeutung der Anatomie des Nierenbeckenkelchsystems in Bezug auf das Defektrisiko der flexiblen Ureterorenoskopie sowie auf Komplikationsrisiken untersucht. Im Rahmen einer retrospektiven, monozentrischen Studie wurde der infundibulopelvine Winkel (IPA) unter Zuhilfenahme der intraoperativen retrograden Pyelographie anhand einer konsekutiven Patientenkohorte gemessen. Hierbei konnte ein steiler IPA als Risikofaktor für Defekte an flexiblen Ureterorenoskopen identifiziert werden. Zudem war der steile IPA mit einem protrahierten postoperativen Verlauf und einer verlängerten Krankenhausverweildauer assoziiert.

Die dritte Publikation (Koautorenschaft) wurde als eine Ergänzung zum Thema Sicherheit der Ureterorenoskopie veröffentlicht. Es wurde ein neues Steinfangkörbchen zur genauen intraoperativen Messung der Steingröße und ureterorenoskopischen Steinextraktion vorgestellt. Die übliche Stahlfeder wurde durch eine Nitinolfeder zur genaueren Einschätzung der Steingröße ersetzt. Eine prospektive Validierung des neuen Konzeptes ist vorgesehen.

Danksagung

An dieser Stelle möchte ich meinen besonderen Dank nachstehenden Personen entgegenbringen, ohne deren Mithilfe die Anfertigung dieser Promotionsschrift niemals zustande gekommen wäre:

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Retrospective Cost Analysis of a Single-Center Reusable Flexible Ureterorenoscopy Program: A Comparative Cost Simulation of Disposable fURS as an Alternative

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Abstract

Objective: The increasing number of flexible ureterorenoscopy (fURS) procedures, the fragility of devices, and their growing maintenance and repair costs represent a substantial burden for urologic departments. Disposable single-use fURS devices offer many advantages over reusable fURS. Among them, the LithoVue™ model shows the best clinical utility. In our study, we assessed the economic aspects of reusable fURS application compared with the potential costs and benefits of single-use fURS (LithoVue™). Indications for single-use fURS were proposed based on potential risk factors of reusable fURS damage.

Materials and Methods: This single-center retrospective analysis compared the actual cost of reusable fURS procedures with the potential costs of LithoVue™ based on the price offered by the manufacturer. Consecutive case analysis of damaged fURS was performed to determine potential risk factors associated with fURS damage.

Results: The study group consisted of 423 reusable fURS procedures conducted between January 2013 and December 2016. During this period, 102 (24.11%) diagnostic fURS and 321 (75.89%) fURS for kidney stone therapy were performed. In 32 of 423 (7.57%) fURS cases, devices were postoperatively deemed defective, 9 of which were used for diagnostic procedures (9/102; 8.82%), 7 for stone removal (7/148; 4.73%), and 16 for stone removal and laser (Ho:YAG) application (16/173; 9.25%). The average cost per reusable fURS procedure was found to be €503.26.

Conclusions: Disposable fURS is a more expensive option for high-volume centers. Based on our case analysis, laser disintegration treatment of multiple, large stones in the lower kidney pole of recurrent stone formers, as well as a steep infundibulopelvic angle (IPA ≤50°), seems to be the main risk factor for fURS damage. For these cases, disposable fURS may be a cost-effective alternative; however, a prospective comparison of economic outcomes between disposable and reusable fURS, together with confirmation of the proposed damage risk factors, is needed.

Keywords: flexible ureterorenoscopy, disposable ureterorenoscopy, cost simulation, damage, LithoVue™

Introduction

Modern flexible ureterorenoscopy (fURS), developed from a pioneer concept by Marshall, gained popularity as a minimally invasive method of endourologic diagnostics and treatment beginning from its early introduction by Bagley in 1987.[1,2] Nowadays, fURS is considered an established method of kidney stone treatment.[3] The rising prevalence of symptomatic kidney stone disease predicts the future global growth of fURS popularity.[4,5]

Despite improvements over the years in regard to miniaturization, passive and active flexion, and digital imaging, fURS instruments are still fragile and prone to damage. The increasing number of fURS procedures, together with the fragility of the devices and growing costs of maintenance and repair, represents a substantial financial and logistic burden for urologic departments worldwide.[6–8]

Optimization of the cost-effectiveness of these devices can be achieved through constant improvements in surgical technique to increase the durability of already established

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reusable instruments.[9,10] Some manufacturers have tackled this problem from a different angle by introducing alternative devices.[11–13]

Already present on the market, disposable single-use fURS devices offer many advantages compared with classical reusable digital or fiber-optic fURS. The LithoVue™ model, manufactured by Boston Scientific, has the highest evidence of clinical utility and is comparable to already validated reusable fURS devices.[14–16]

To our knowledge, only one cost analysis has been conducted to date, which compared the real costs of reusable fURS with the anticipated costs of disposable fURS (LithoVue™).[17] Martin et al. conducted a prospective summary of the annual costs of 160 reusable fURS procedures, as well as the repair costs, with a limited description of 11 fURS cases with proven device damage during the same period. Based on this study, reusable fURS was determined to be a far more cost-effective option for high-volume centers in the United States compared with LithoVue™. Further cost analyses, together with the identification of risk factors for fURS damage, are urgently needed.

The aim of our study was to retrospectively assess the economic aspects of application of reusable fURS in a single-center clinical setting, to compare the actual costs with the potential costs of LithoVue™ based on the price offered by the manufacturer, as well as to perform case analysis of damaged fURS to identify potential risk factors for fURS damage.

Materials and Methods

We retrospectively analyzed all fURS cases performed using only reusable fURS at our center between January 2013 and December 2016. Between 2013 and 2015, all fURS surgeries were performed with seven reusable Karl Storz Flex-X2 devices. The real costs consisted of the purchase of three new devices (Olympus URF-V), in service from 2016, the repair costs, as well as the reprocessing cost based on the internal labor cost of designated hospital workers and the fixed sterilization fee of €123 per case (external contract with Vanguard AG). The aforementioned labor cost was estimated to be €20 per case. Postoperatively, the devices were cleaned, tested for leakproofness, disinfected with 30 mL of 1% Gigasept PAA (Schülke & Mayr GmbH), dried, and prepared for transport for external sterilization. This process took around 60 minutes and was conducted by a designated hospital worker.

There was an additional cost of repair of defective fURS by an external outsourced company (Drägerwerk AG & Co. KGaA). The fURS devices that were deemed defective during routine postoperative processing were exchanged for new devices by the manufacturer. The cost of seven Karl Storz Flex-X2 devices that had been purchased before 2013 was not included in our analysis. The real costs and the average cost per procedure were compared with the anticipated cost of the same number of LithoVue™ procedures.

In addition, we conducted a detailed case analysis of damaged fURS to identify factors that could be considered candidates as risk factors for fURS damage. The infundibulopelvic angle (IPA) was measured in accordance with the El-Bahnasy definition.[18] The angle was measured between the ureteropelvic axis and central axis of the lower pole infundibulum based on retrograde pyelography images (Figs. 1 and 2).

FIG. 1. Retrograde pyelography: IPA ≤50°. IPA = infundibulopelvic angle.

Results

During the given period (January 2013–December 2016), 423 (100%) fURS procedures were performed, 102 (24.11%) of which were diagnostic procedures and 321 (75.89%) for kidney stone therapy. The latter subgroup consisted of

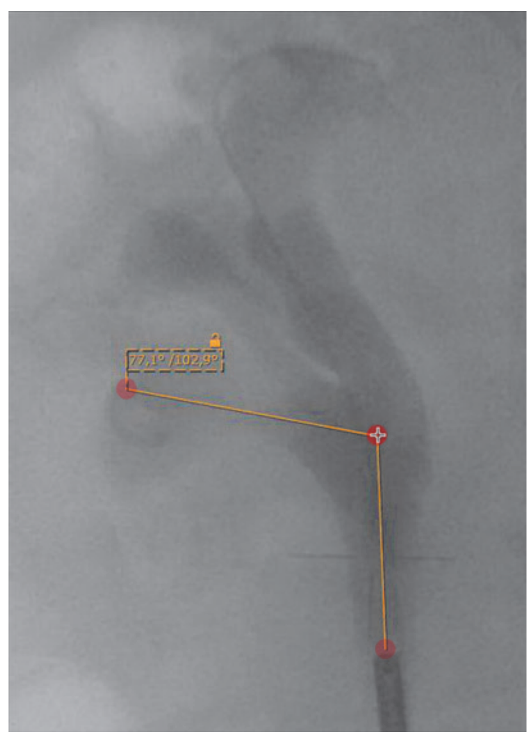

FIG. 2. Retrograde pyelography: IPA >50°.

148 (34.99%) fURS for stone removal and 173 (40.9%) fURS for stone removal combined with laser (Ho:YAG) application.

In 32 out of 423 (7.57%) fURS cases, the devices were postoperatively deemed defective and required repair. Of these, 9 had been used for diagnostic fURS (9/102; 8.82%), 7 for fURS with stone removal (7/148; 4.73%), and 16 for fURS with stone removal and laser (Ho:YAG) application via fURS (16/173; 9.25%). Thirty-one of 32 (96.86%) cases with proven fURS damage involved exploration of the lower kidney pole. Twenty out of 23 (86.96%) managed stones were located in the lower kidney pole. The stones that were managed with subsequent fURS damage had a mean diameter of 8 mm (standard deviation [SD] ±6.67 mm) and a mean density of 918 HU (SD ±292 HU). The mean operation time for cases with fURS damage was 80 minutes (SD ±32 minutes). More than half of the damaged fURS cases (18/32; 56.25%) demonstrated a steep IPA ≤50°. Stone-free status was achieved in less than half of cases (10/23, 43.48%). Repair reports revealed two main causes of fURS damage: device leakiness (18/32; 56.25%) and tip break-off (7/32; 21.86%). The average number of cases resulting in fURS damage was estimated to be 14.4. Detailed results regarding damaged fURS are presented in Tables 1 and 2.

The total cost of all fURS procedures was estimated to be €212,880.02. The average cost per fURS procedure was €503.26. A detailed summary of the costs is presented in Table 3. The assumed price per LithoVue™ device was €1000.

Table 1. Damaged Flexible Ureterorenoscopy: Preoperative Characteristics

Number of patients	32
Male/female	21/11
Age	58 (SD ± 18)
Affected side	
Left	21 (65.63%)
Right	11 (34.37%)
Double-J prestenting	26/32 (81.25%)
fURS indication	
Diagnostic	9/32 (28.13%)
Kidney stone	23/32 (71.87%)
Recurrent urolithiasis patients	14/23 (60.87%)
Recent urolithiasis procedures	
SWL	5/23 (21.74%)
URS	5/23 (21.74%)
PNL	2/23 (8.69%)
Stone characteristics	
Single stone	9/23 (39.13%)
Multiple stones	14/23 (60.87%)
Stone diameter	8 (SD ± 6.67)
<10 mm	12/23 (52.17%)
10–20 mm	8/23 (34.78%)
>20 mm	3/23 (13.04%)
Stone density (HU)	918 (SD ± 292)
Stone location	
Lower pole	20/23 (86.96%)
Upper pole	1/23 (4.35%)
Renal pelvis	2/23 (8.69%)
Concomitant ureteral stone	7/23 (30.43%)

fURS = flexible ureterorenoscopy; PNL = percutaneous nephrolithotomy; SD = standard deviation; SWL = extracorporeal shockwave lithotripsy.

Table 2. Damaged Flexible Ureterorenoscopy: Intraoperative Characteristics

Mean operation time	80 minutes (SD ±32 minutes)
Laser (Ho:YAG) application	
Via fURS	16/32 (50%)
Median total laser energy (kJ)	
Via fURS	1,2
fURS insertion	
Besides safety guidewire	6/32 (18.75%)
Over the guidewire	18/32 (56.25%)
Ureteral access sheath	8/32 (25%)
Lower pole inspection	31/32 (96.88%)
Infundibulopelvic angle (retrograde pyelography)	
≤50°	18/32 (56.25%)
>50°	10/32 (31.25%)
No data	4/32 (12.5%)
Stone-free rate	10/23 (43.48%)
Repair reports	
Leakiness	18/32 (56.25%)
Tip break-off	7/32 (21.86%)
Other cause	7/32 (21.86%)

Discussion

Our study, conducted without subgroup analysis, confirmed general higher cost-effectiveness of reusable fURS for high-volume stone therapy centers.

In many urologic centers that schedule surgeries for stone treatment, the OR capacity is strongly dependent on the availability of the limited number of fURS devices. Unplanned fURS application (e.g., push-back stones scheduled for semirigid URS without an fURS device on standby) also diminishes the capacity of fURS. As observed in clinical practice, prolonged waiting time for surgery may be associated with unnecessary stress and dissatisfaction for some patients,[19] as well as economic losses for the department.

Single-use devices could represent an alternative to limited availability of reusable fURS by shortening waiting lists and providing more options for the surgeon in cases where the indication for fURS occurs intraoperatively.

Despite any possible inaccuracies of our analysis, we have shown that the economic difference between single-use (€1000 per LithoVue™) and reusable (€503.26 per case) fURS is substantial. Therefore, our reusable fURS program is more cost-efficient, despite some of the advantages of LithoVue™ such as better visibility and maneuverability, best possible brand new device availability[20] and a reduced risk of infection transmission. Disposable fURS can be

Table 3. Costs of Reusable Flexible Ureterorenoscopy Program 2013–2016

	Diagnostic fURS	*fURS for kidney stones*	*Per Case*
fURS cases	102	321	
Repairs	€24,534.54	€77,654.48	€241.58
Reprocessing	€14,586.00	€45,903.00	€143.00
New devices	€50,202.00		€118.68
Total cost	€212,880.02		€503.26

considered a good option for endourologic treatment in developing countries, where the resources necessary to service and maintain reusable devices are limited.

Beginning in 2016, procedures were performed with two types of fURS devices. Only one case performed with an Olympus URF-V resulted in instrument damage at that time. No procedures were performed using the Olympus URF-V between 2013 and 2015. Thus, we were unable to make any conclusions regarding differences in durability between the two available reusable fURS devices.

Most of the fURS defects occurred in complex cases of kidney stone disease characterized by multiple, large, dense stones, especially those located in the lower kidney pole, that required laser disintegration with application of laser fiber through the fURS working channel. In the majority of cases, the patients were recurrent stone-formers, and stone-free status was not achieved during the usually time-consuming procedure. This group of patients could be an interesting target for application of single-use fURS to prevent future damage.

Detailed analysis of the risk factors for fURS damage identified not only fURS applied for kidney stone therapy but also a proportional number of diagnostic procedures (9/102; 8.82%). The working channel was used for biopsy in only two out of nine cases. Hence, there must be another device damage mechanism that is not directly associated with the use of the working channel with tools such as laser fibers, baskets, or biopsy forceps. A steep IPA ≤50° was confirmed in intraoperative retrograde pyelography in over half of the analyzed cases. Our data and experience suggest that extreme flexion of the tip to reach the lower kidney pole, especially when trying to reach a ventral calyx, could play a role in the fURS damage mechanism.

Almost 50% of arising costs (€102,189.02) were due to the repair of 32 damaged devices. If these cases had been recognized preoperatively and conducted with LithoVue™, our department could have saved enough to cover 70 additional LithoVue™ procedures. The improved fURS capacity by this means could have reduced the number of new Olympus URF-V devices that were purchased in 2016 and, consequently, resulted in further savings.

The pre- and intraoperative risk factors of fURS damage proposed in this article should be confirmed in future comparative studies. Thus, cases in which application of single-use fURS is a cost-effective alternative can be identified.

The retrospective nature of our study can be considered a limitation. Aside from solid data regarding the purchase cost of new devices and the reprocessing and repair costs, additional internal costs that are difficult to quantify should also be taken into consideration. A lack of precise financial data regarding factors such as cleaning materials, storage, and labor, in particular, has led to cost estimation only. For instance, the labor costs to maintain and disinfect already used fURS should not only be considered expenses for wages proportional to time but also as a loss due to the inability of workers to fulfill other clinical tasks during that time. It should be noted that the presented costs are specific to our department, and variability between institutions with regard to processing protocol or personnel is likely.

The cost of the seven Karl Storz Flex-X2 devices that were already in use at the beginning of 2013 was purposefully not included in our analysis. Our study was designed to analyze the expenses associated with a theoretical shift from reusable to single-use devices, not to assess the cost of commencing single-use fURS programs in centers with no fURS equipment. In summary, the low cost of our reusable fURS program is consistent with previously published results showing economic superiority of fURS programs based on reusable devices over the application of single-use instruments only.[17]

Conclusions

Shifting from reusable fURS to disposable fURS only may be a more expensive option for high-volume centers. The treatment of multiple, large stones in the lower kidney pole of recurrent stone-formers with laser disintegration, as well as a steep IPA, appears to be the main risk factor for fURS damage. For these cases in particular, disposable fURS may be a more cost-effective alternative. A better understanding of the damage mechanisms is key for a proper indication to use the more expensive single-use device. Prospective comparison between disposable and reusable fURS in regard to economic outcomes, together with confirmation of damage risk factors, is needed.

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Abbreviation Used

fURS = flexible ureterorenoscopy
Ho:YAG = holmium YAG laser
HU = Hounsfield units
IPA = infundibulopelvic angle
kJ = kilojoule
PNL = percutaneous nephrolithotomy
SD = standard deviation
SWL = extracorporeal shockwave lithotripsy
URS = ureterorenoscopy

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Steep Infundibulopelvic Angle as a New Risk Factor for Flexible Ureteroscope Damage and Complicated Postoperative Course

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Abstract

Objective: The increasing number of flexible ureterorenoscopy (fURS) procedures, the fragility of devices, and their growing repair costs represent a substantial burden for urological departments worldwide. No risk factors of flexible ureteroscope damage have been identified so far. The objective of this study was to investigate the impact of infundibulopelvic angle (IPA) on device damage and on other intraoperative and postoperative factors such as length of hospital stay, surgical complications, stone-free rate (SFR), operation, and fluoroscopy time.
Materials and Methods: In a retrospective monocentric study, IPA was measured based on intraoperative retrograde pyelography images taken during fURS. All procedures were conducted with modern reusable flexible ureteroscopes: Karl Storz Flex-X2 or Olympus URF-V. Statistical analysis was performed in RStudio (version 1.0.136) with the unpaired *t*-test and Mann–Whitney U test. Pearson correlation coefficient (Pearson's *r*) was measured whenever applicable.
Results: In total, 381 fURS performed between September 2013 and March 2017 were analyzed: 260 (68.24%) for kidney stone operation and 121 (31.76%) for diagnostic purposes; of these, 38 (9.97%) devices were postoperatively deemed defective. IPA values were significantly steeper in cases with flexible ureteroscope damage compared to cases without damage (median 42.5 degrees *vs* 56.0, $p<0.001$). Steeper IPA was significantly associated with the occurrence of Clavien-Dindo ≥2 complications (median 51.0 degrees *vs* 55.0, $p=0.005$) as well as prolonged hospital stay (median 51.0 degrees *vs* 55.0, $p=0.014$). No influence on SFR was observed ($p>0.05$). IPA did not correlate with operation or fluoroscopy time.
Conclusions: Steep IPA can be considered the first risk factor predicting both flexible ureteroscope damage and an unfavorable postoperative course. A better understanding of damage mechanisms is the key for the proper indications to use costly single-use devices.

Keywords: infundibulopelvic angle, flexible ureterorenoscopy, flexible ureteroscope damage, complications

Introduction

Modern flexible ureterorenoscopy (fURS), developed from a pioneering concept by Marshall, gained popularity as a minimally invasive method of endourologic diagnostics and treatment beginning from its early introduction by Bagley in 1987.[1,2] Nowadays, this minimally invasive approach is considered a first-choice treatment for the majority of kidney stones, especially for lower pole stones <2 cm.[3] It can be expected that because of the growing prevalence of kidney stone disease, the demand on flexible ureteroscopes will increase.[4,5]

The fragility of flexible ureteroscopes, a growing number of procedures worldwide, as well as the associated maintenance and repair costs, are important economic and logistic challenges for endourologic centers performing fURS procedures.[6–8] Despite many improvements over the past years, such as miniaturization, passive and active flexion, and digital imaging, the susceptibility to intraoperative damage is still high and has become a major point of scientific interest over recent years.

The identification of risk factors of reusable flexible ureteroscope damage would be beneficial in terms of identifying indications for disposable fURS, to decrease the rates

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of reusable fURS device damage. Our own data and experience suggest that extreme flexion of the tip of fURS devices to overcome a steep infundibulopelvic angle (IPA) and reach the lower kidney pole could play a role in fURS damage mechanism.[9]

The substantial influence of IPA on radiologically confirmed stone-free rate (SFR) as well as stone clearance after fURS and shockwave lithotripsy (SWL) procedures was already confirmed in retrospective[10–13] as well as prospective studies.[14] Based on those findings, the steep IPA was recognized in the Guidelines of the European Association of Urology as a factor that negatively influences stone clearance from the lower kidney pole after SWL procedures.[3]

The aim of this study was to investigate whether the IPA would play a role as a risk factor of fURS device damage. The relationship of IPA to other intraoperative and postoperative factors such as complication rate, fluoroscopy time, and length of hospital stay (LOS) has also been studied.

Materials and Methods

Our retrospective monocentric study was based on 381 fURS cases performed between September 2013 and March 2017 at the Department of Urology, University Hospital Schleswig-Holstein (Luebeck, Germany). Written patient consent was obtained. Preoperative antibiotic therapy was applied only in patients with positive preoperative urine culture. Patients were operated under general anesthesia in supine lithotomy position. All procedures were conducted with modern reusable flexible ureteroscopes: Karl Storz Flex-X2 and Olympus URF-V.

In the majority of cases, fURS was preceded by semirigid ureterorenoscopy (URS).

The IPA was measured based on intraoperative retrograde pyelography (RPG) images. Contrast (Urolux Retro®; CS Diagnostics GmbH) was usually injected into the proximal ureter through the semirigid ureteroscope, before the application of fURS devices. Stone lithotripsy was conducted with SlimLine 200 μm Fiber (Boston Scientific) and Holmium Laser (Lumenis VersaPulse® PowerSuite™ 100 W). Uromed Stonizer® tipless (1.9F) or NGage® (2.2F) nitinol baskets were used for kidney stone extraction. Tissue biopsies were performed with Olympus FB 56D-1 (1.2 mm) or Karl Storz (3.0F) biopsy forceps. Inspection of all calices, including lower kidney pole, belongs to the state of the art of every fURS procedure performed in our department. Ureteral stent reinsertion was dependent on the complexity level of the given operation and the extent of postoperative ureteral trauma; thus, it was not performed routinely.

Postoperatively, the devices were cleaned, tested for leakproofness, disinfected with 30 mL of 1% GIGASEPT PAA (Schülke & Mayr GmbH), dried, and prepared for transport for external sterilization. The fURS devices that were deemed defective during routine postoperative processing were sent to external repair (Drägerwerk AG & Co. KGaA) and exchanged for new devices by the manufacturer.

Stone-free status was usually determined intraoperatively by the surgeon. Radiological reevaluation with CT or kidney, ureter, and bladder radiograph (KUB) was conducted only in cases of uncertainty regarding postoperative stone-free status or before second-look procedures.

The IPA was retrospectively digitally measured (Agfa HealthCare IMPAX Software) in accordance with the El-Bahnasy definition.[15] The angle was measured between the ureteropelvic axis and central axis of the lower pole infundibulum based on recorded intraoperative RPG images (Fig. 1).

Analyzed parameters included SFR, fURS device defects, intraoperative and postoperative complications, LOS, operation and fluoroscopy time, recurrent stone former status, and presence of lower pole kidney stones.

Recurrent stone former was defined as a patient with at least one stone event in the past. The fURS devices were deemed defective during routine postoperative processing. Intraoperative and postoperative complications were classified based on the Clavien-Dindo scale.[16] Routine hospital stay in our department is dependent on current reimbursement system and limited to 48 postoperative hours.

Statistical analysis was performed by RStudio (version 1.0.136). Mean value with standard deviation for normally distributed variables, median value with minimum and maximum values for variables without normal distribution, as well as percent values for categorical variables were used for descriptive statistics. Normal distribution was tested with the Shapiro–Wilk test. Depending on its results, the unpaired *t*-test or Mann–Whitney U, or Pearson correlation test was applied for univariate analysis. The level of significance was defined as $p < 0.05$.

Results

In total, 381 fURS performed between September 2013 and March 2017 were analyzed: 260 (68.24%) for kidney

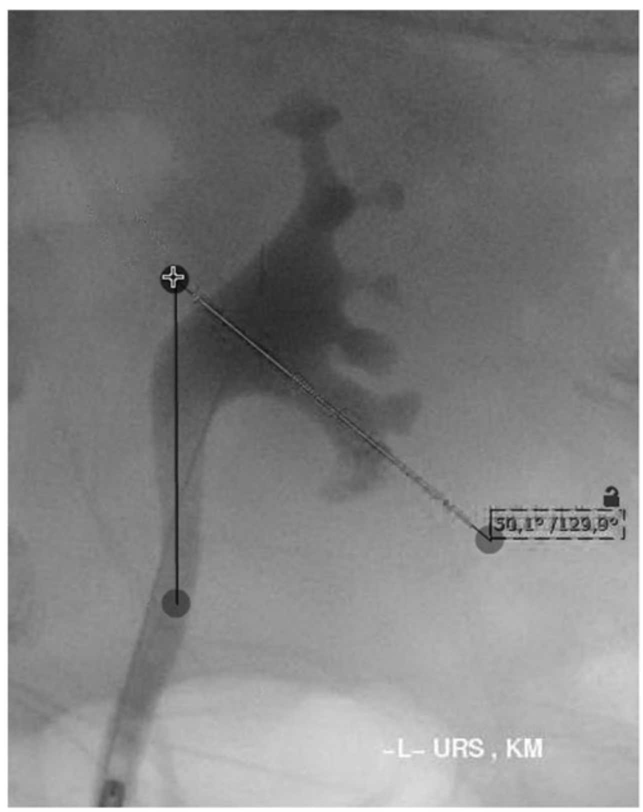

FIG. 1. Infundibulopelvic angle of 50 degrees. URS = ureterorenoscopy.

stone operation and 121 (31.76%) for diagnostic purposes. Preoperative characteristics are presented in Table 1. The majority of therapeutic fURS involved lower pole stones (194/260, 74.62%) and stones <2 cm (254/260, 97.69%). In 38 (9.97%) cases, devices were postoperatively deemed defective. Presence of lower pole kidney stones was observed in 23 out of 38 fURS (60.53%) cases with device damage.

Device leakage (23/38, 60.53%) and defects of Bowden cable system (7/38, 18.42%) were two major recorded causes of device defect.

Median IPA in the analyzed cohort was 54.0 degrees. Extended postoperative hospital stay (>2 days) was noted in 56 (14.93%) cases. Detailed intraoperative and postoperative characteristics are presented in Table 2.

Significant complications requiring at least an additional pharmacological treatment (Clavien-Dindo ≥2) occurred in 39 (10.24%) patients. The majority of recorded complications (Table 3) were associated with postoperative urinary tract infection (27/39 cases, 69.23%), requiring antibiotic therapy (Clavien-Dindo grade 2). In one case, Double-J stent reinsertion (Clavien-Dindo grade 3b), and in two cases, intensive therapy (Clavien-Dindo grade 4) were necessary because of postoperative sepsis. Mortality was limited to one case of postoperative pneumonia.

In univariate analysis, significantly steeper IPA values correlated with damaged fURS devices (median 42.5 degrees *vs* 56.0, $p<0.001$). A steep IPA was also significantly associated with the occurrence of Clavien-Dindo ≥2 complications (median 51.0 degrees *vs* 55.0, $p=0.005$), as well as a prolonged hospital stay (median 51.0 degrees *vs* 55.0, $p=0.014$).

Table 1. Preoperative Characteristics

No. of cases	381
Male/female	254/127
Mean age (years)	57.09 (SD ±16.83)
Affected side	
Left	203/381 (53.28%)
Right	178/381 (46.72%)
Presenting	348/381 (91.33%)
fURS indication	
Diagnostic	121/381 (31.76%)
Kidney stone disease	260/381 (68.24%)
Recurrent stone formers	135/381 (35.43%)
Kidney stone characteristics	
Single stone	125/260 (48.08%)
Multiple stones	135/260 (51.92%)
Mean maximal stone diameter (mm)	7.11 (SD ±4.27)
<l0 mm	199/260 (77.61%)
10–20 mm	55/260 (21.15%)
>20 mm	2/260 (0.77%)
No data	4/260 (1.54%)
Mean stone density (HU)	846.31 (SD ±314.37)
Kidney stone location	
Lower calix	194/260 (74.62%)
Singular lower calix stone	76/260 (29.23%)
Middle calix	67/260 (25.77%)
Upper calix	39/260 (15.00%)
Renal pelvis	39/260 (15.00%)
Ureteral stone	105/381 (27.56%)

Percentages and SDs for mean values in brackets.
fURS = flexible ureterorenoscopy; SD = standard deviation.

Table 2. Intraoperative and Postoperative Characteristics

Mean operation time	73.23 (SD ±36.31)
≥60 minutes	209/381 (54.86%)
≥90 minutes	115/381 (30.18%)
No data	11/381 (2.89%)
Holmium laser application	175/381 (45.93%)
By fURS	110/381 (28.87%)
Median total laser energy (kJ)	0.965 (0.01; 7.74)
By fURS	1.215 (0.02; 7.1)
Median fluoroscopy time (seconds)	70 (8; 920)
Biopsy	32/381 (8.40%)
By fURS	24/381 (6.30%)
Flexible ureteroscope insertion	
Without safety guidewire	79/381 (20.73%)
With safety guidewire	290/381 (76.12%)
Ureteral access sheath	90/381 (23.62%)
No data	13/381 (3.41%)
Median RPG IPA (degrees)	54.0 (7.0; 122.0)
SFR (overall for kidney stones)	191/260 (73.46%)
Lower pole stones	138/194 (71.13%)
Singular lower pole stones	59/76 (77.63%)
Length of postoperative hospital stay[a]	
>2 days	56/375 (14.93%)
No data	2/375 (0.53%)
Clavien-Dindo ≥ grade 2	39/381 (10.24%)
Flexible ureteroscope defect	38/381 (9.97%)
Diagnostic fURS	9/121 (7.44%)
Kidney stone fURS	29/260 (11.15%)

Percentages, SDs for mean values and minimum/maximum for median values in brackets.
[a]Six cases excluded—consecutive procedure (e.g., nephrectomy) during the same hospital stay.
IPA = infundibulopelvic angle; RPG = retrograde pyelography; SFR = stone-free rate.

Figure 2 presents in detail boxplots of these significant parameters. No influence on SFR or operation time was observed ($p>0.05$, Table 4).

The linear model did not reveal any significant correlation between IPA and operating time (Pearson's $r=0.036$, $p=0.486$), or between IPA and fluoroscopy time (Pearson's $r=0.022$, $p=0.672$).

Table 3. Intraoperative and Postoperative Complications

Complication	*Clavien-Dindo grade*	*No. of patients*
Bleeding complications	1	12/381 (3.15%)
	2	4/381 (1.05%)
Urinary tract infection	2	24/381 (6.30%)
	3b	1/381 (0.26%)
	4	2/381 (0.52%)
Perforation of the upper urinary tract	2	5/381 (1.31%)
Pneumonia	4	1/381 (0.26%)
	5	1/381 (0.26%)
No data		2/381 (0.52%)

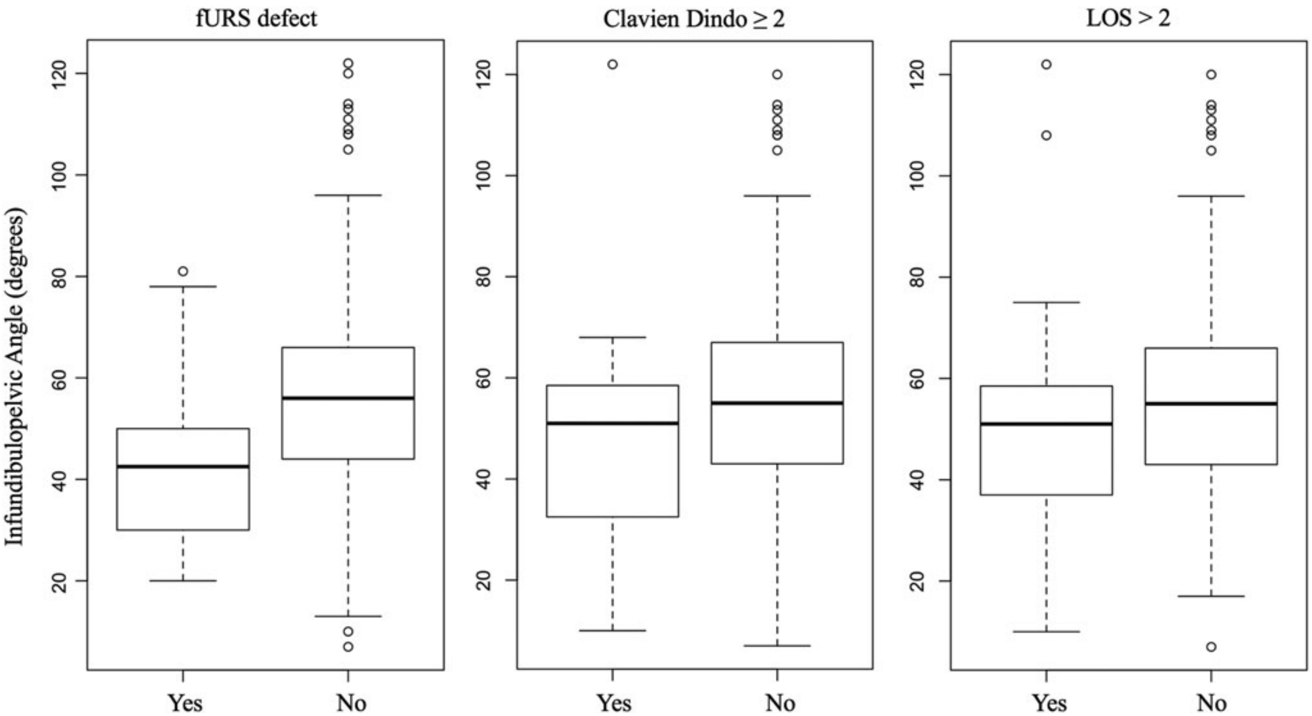

FIG. 2. Box plots of statistically significant parameters ($p < 0.05$). fURS = flexible ureterorenoscopy; LOS = length of hospital stay.

Discussion

To our knowledge, we present the first analysis of data revealing significant relationships between the anatomy of the collecting renal system and the damage rate of reusable fURS devices.

Our results suggest that a steep IPA, regardless of the complexity of the stone retrieval, influences the durability of reusable devices. Moreover, we noticed that relatively many defects occurred in diagnostic procedures (9/121; 7.44%). Therefore, it is possible that the IPA plays a role in device damage not only in typical cases with lower pole kidney stones. This hypothesis should be confirmed in further studies.

The vast majority of fURS defects occurred when the measured IPA reached 60 degrees or less (33/38 cases, 86.84%). One out of four cases with an IPA ≤35 degrees resulted in a postoperative flexible device defect (17/61, 27.87%). Based on these results, the IPA may be implemented in routine clinical practice for the identification of appropriate surgical measures to preserve reusable fURS devices by using costly single-use fURS devices instead.

A steep IPA was additionally associated with a prolonged hospital stay and the prevalence of intraoperative and postoperative complications (Clavien-Dindo ≥2). Thus, this group of patients demands not only careful performance by the surgeon but also additional attention during the postoperative period.

The cost-effectiveness with regard to fURS may be improved through some advancements in surgical techniques and resident training, to increase the longevity of already established reusable instruments.[17,18] On the other hand, already mentioned disposable fURS devices have been recently introduced as an alternative to traditional reusable flexible ureteroscopes.[19–21] Among the different devices,

Table 4. Univariate Statistical Analysis with Median Values of Infundibulopelvic Angle

	Yes	*No*	p	*Test*
fURS defect	42.5 (20.0; 81.0)	56.0 (7.0; 122.0)	*<0.001*	MWU
Clavien-Dindo ≥2	51.0 (10.0; 122.0)	55.0 (7.0; 120.0)	*0.005*	MWU
LOS >2 days	51.0 (10.0; 122.0)	55.0 (7.0; 120.0)	*0.014*	MWU
Operation time ≥60 minutes	56.0 (10.0; 120.0)	53.5 (7.0; 122.0)	0.172	MWU
Operation time ≥90 minutes	56.0 (23.0; 120.0)	54.0 (7.0; 122.0)	0.604	MWU
Stone free (overall for kidney stones)	55.0 (19.0; 120.0)	52.5 (7.0; 95.0)	0.214	MWU
Stone free (lower pole stones only)	53.85* (SD ±17.49)	52.57* (SD ±18.30)	0.654	*t*-test
Recurrent stone former	54.0 (10.0; 105.0)	55.5 (7.0; 122.0)	0.081	MWU
Lower pole stone presence	53.0 (7.0; 113.0)	57.0 (10.0; 120.0)	0.438	MWU

Minimal and maximal values in brackets. Italic values characterize statistically significant parameters.
*Mean value.
LOS = length of hospital stay; MWU = Mann–Whitney U test.

the LithoVue™ (Boston Scientific) has the highest level of clinical evidence of clinical utility.[22]

In terms of efficacy and safety, the LithoVue has been shown to not be inferior in comparison to reusable devices based on prospective trials.[23–25] However, recently published cost analyses demonstrated higher costs in the routine use of single-use fURS devices over reusable flexible ureteroscopes for high-volume stone therapy centers.[9,26]

Current data regarding risk factors for fURS device damage are scarce. The available literature focuses mostly on economic aspects of the usage of reusable flexible ureteroscopes, usually in comparison to single-use devices.[9,26,27]

Martin et al.[26] prospectively summarized the annual costs of 160 reusable fURS procedures, including repair costs. Eleven cases with proven reusable fURS device damage were recognized in the same period. Based on this study, reusable fURS was determined to be a more cost-effective alternative for high-volume endourologic centers in the United States compared to disposable fURS, such as LithoVue. The average cost of reusable fURS revealed amortized costs of ∼$850 per use. However, the authors did not propose any specific risk factor of fURS device damage in their study.[26]

Our working group also showed an economic superiority of reusable fURS in a retrospective cost simulation of an fURS program in a German setting.[9] The average cost of reusable fURS was ∼€500 per procedure. Moreover, it was observed that the fURS defects occurred usually in complex cases of kidney stone disease characterized by multiple, large dense stones, located particularly in the lower kidney pole that required laser disintegration with the necessary application of a laser fiber through the fURS working channel.

Based on the results of this study, we assume that not only preoperative stone status but also the anatomy of the renal collecting system, especially IPA, may be an important factor, which should be considered in future prospective trials that are designed to identify risk factors of reusable device damage and indications for disposable fURS.

Our Olympus devices are being used since 2016 and constitute minority of our equipment (3 Olympus URF-V *vs* 7 Karl Storz Flex-X2). Unfortunately, we possess the information regarding ureteroscope type only for the cases with reported device damage. To sum up, gathered data are not sufficient to determine which device type provides better performance and durability.

The absence of influence of overall IPA on the operation time and on the SFR based on intraoperative evaluation corresponds with the already published data of Jessen et al.[11]

This supports the conclusion that modern fURS devices provide good performance regardless of the renal anatomy. It seems that the excellent flexion of modern flexible ureteroscopes guarantees good performance regardless of the stone position. Taking our study into consideration, it should be recommended that different endourologic tools as baskets, laser fibers, and biopsy forceps should be introduced only when the tip of flexible ureteroscope is straight positioned. Based on our experience, which stands in line with described results, the direct insertion of mentioned tools in deflected tip of ureteroscope to directly reach lower calix may result in ureteroscope leakage.

As already mentioned, stone-free status was determined intraoperatively by the surgeon. A more objective evaluation could be achieved by postoperative CT or KUB. Clinical practice in our department, however, supports the reduction of radiologic exposure to the patients in cases where intraoperative stone freedom is not questionable.

The IPA was measured retrospectively on RPG images taken intraoperatively. Contrast was usually applied through a semirigid URS device. The force generated by the insertion of a semirigid URS could cause ureter dislocation, thereby influencing measured IPA values.

The retrospective nature of our study is considered a limitation. Thus, the history of each reusable device was not tracked; we were unable to determine if the number of previous procedures or the type of ureteroscope had an impact on the risk of damage. Further case–control and prospective studies focused on finding other intraoperative and postoperative risk factors of flexible ureteroscope damage are needed. Assessment of other known radiological parameters regarding renal collecting system (e.g., infundibular length and width) was not possible because of retrospective character of the study. The accurate measurement of these parameters requires a defined distance between the patient's kidney and X-ray source. In retrospective setting, it was impossible to reproduce this value. Similar prospective analysis of overmentioned anatomical factors would be surely interesting for the future.

Conclusions

A steep IPA can be considered the first risk factor predicting both reusable fURS device damage and a complicated postoperative course. Special intraoperative and postoperative attention in cases with a steep IPA of 60 degrees or less are advised. A better understanding of damage mechanisms is key for the proper indication to use costly single-use devices. The significance of IPA as a risk factor has to be validated in prospective trials.

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Author Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

CT = computer tomography
fURS = flexible ureterorenoscopy
HU = Hounsfield units
IPA = infundibulopelvic angle
KUB = kidney, ureter, and bladder radiograph
LOS = length of hospital stay
MWU = Mann–Whitney U test
RPG = retrograde pyelography
SD = standard deviation
SFR = stone-free rate
SWL = shockwave lithotripsy
URS = ureterorenoscopy

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ORIGINAL RESEARCH

A New Automatically Fixating Stone Basket (2.5 F) Prototype with a Nitinol Spring for Accurate Ureteroscopic Stone Size Measurement

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ABSTRACT

Introduction: Intraoperative assessment of stone size is crucial for the successful and safe extraction of stones. The first automatically fixating measuring stone basket prototype showed a mismatch between the steel spring and the nitinol basket; therefore, to improve this prototype, the steel spring was replaced with a nitinol spring and a modified scale was implemented on the basket handle for accurate intraoperative stone size measurement.
Methods: The proposed tipped basket was composed of nitinol. A standard handle with a spring-supported self-closing mechanism (2.5 F, Urotech®) was used, and a modified nonlinear millimeter scale was established on the handle. The grasping force was provided by the new nitinol spring mechanism in the handgrip. Various colors associated with the stone size were applied on the scale.
Results: The material difference between the basket and the spring was eliminated. The measuring scale ranged from 2 mm (green) through 5 mm (yellow) to 8 mm (red), and the scale was nonlinear because of the nonlinear relationship between the diameter of the stone and the distance marked on the scale.
Conclusion: The proposed automatically fixating stone basket with a nitinol spring has the potential to improve the safety and effectiveness of endourological stone retrieval. Further validation of this new scale and basket should follow.

Keywords: Endourology; Nitinol; Stone basket; Stone measurement; Ureteroscopy

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INTRODUCTION

Ureteroscopy (URS) is currently the first-choice therapy for ureteral stones and is the recommended therapy option for kidney stones smaller than 2 cm [1]. The growing prevalence of kidney stone disease worldwide and the favorable characteristics of URS (i.e., low invasiveness, high stone-free rates, and relatively low risk of intra- and postoperative complications) predict that there will be a growing demand for URS in the future [2, 3].

Low-dose noncontrast computer tomography (CT) is the gold standard for the diagnosis of acute flank pain and therefore for the

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preoperative planning of endourological treatment [4]; however, in certain settings, the accuracy of CT-based preoperative stone size assessment, especially regarding ureteral stones, may be inaccurate [5]. Moreover, Patel et al. revealed that the CT-based estimation of stone diameter for larger stones (≥ 4 mm) may be less precise than intraoperative visual assessment by the surgeon [6]. Thus, additional reliable stone size assessment during URS would be helpful for making decisions about whether to perform direct stone extraction or laser lithotripsy for larger stone fragments.

Current literature regarding the unique concept of a stone size measuring basket is scarce.

Our research group previously introduced a nonlinear millimeter scale coupled with various self-closing nitinol stone baskets (2.5, 3.0, and 4.0 F) to enhance intraoperative stone size measurements [7]. The nonlinear millimeter basket scale was compared in vitro with the visual estimation of two surgeons, and manual stone measurement was used as the reference method. The 2.5-F nitinol basket was the most accurate for measuring larger stones (> 6 mm) with sensitivity of 56% and specificity of 84%, while the 4.0-F basket was the most accurate for smaller stones (< 3 mm); however, the study showed that the visual ureteroscopic estimation was superior to the basket measurement [8]. The basket system could have been inferior to visual assessment as a result of a mismatch between the steel spring and the nitinol basket, which may have influenced the measurement accuracy depicted on the scale. The different material-specific relationships of steel and nitinol regarding their stress and strain could explain this phenomenon. Initially steel is not flexible and shows increasing stress during engaging the stone, whereas nitinol shows more strain and less stress. Even less stress is present during the reverse action [9].

Therefore, to resolve the described mismatch and to improve the measurement accuracy, a new basket prototype, especially for ureteral and renal pelvic stones, has been proposed in which the steel spring has been replaced with a nitinol spring.

METHODS

The tipped automatically fixating stone basket was composed of nitinol to provide maximal safety to the surrounding urothelial tissue and best possible performance. The steel spring was replaced with a suitable nitinol spring as a part of the stone-fixating mechanism. The slider on the front side of the handle opens the basket and enables the stone to be grasped (Fig. 1).

A standard handle (Urotech®) connected to a 2.5-F basket was described previously [7, 8] and was used in this prototype. It was developed in cooperation with Prof. S. Lahme (Pforzheim, Germany). The handle has two unique design elements: firstly, it has a mentioned spring mechanism that enables automatic stone fixation in the basket; secondly, it is equipped with a dis- and reconnectable handle so that the

Fig. 1 A handle with a new colored millimeter scale and slider

ureteroscope can be fully removed while the retrieval basket with the grasped stone remains in place. The handle can be reconnected again if needed. The handle should be opened on the back side to disconnect the basket (Fig. 2), as this maneuver enables a switch to be made between different URS devices without the need to disengage the stone.

A modified nonlinear millimeter scale was established on the handle. The scale was standardized by grasping standardized (DIN "Deutsche Industrie Norm" ISO 281) screws with the basket. Various colors on the millimeter scale were applied, and the color change from green to yellow was based on the study by Abdelrahim et al. They showed that stones greater than 5 mm in width are associated with a statistically significant higher incidence of intraoperative complications [10]. The color change from yellow to red was a proposal by the author and should be further investigated.

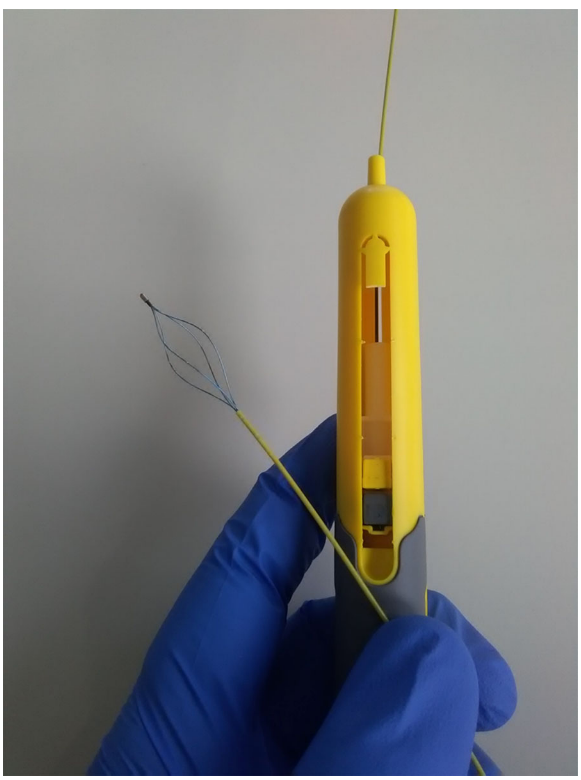

Fig. 2 The opened back of the handle demonstrates the slider in an opened-basket position. The nitinol spring is in the proximal gray part of the handle

Extreme caution should be applied during manipulation of the stones situated in the red area because of their size. The development of the presented prototype did not contain any studies with human participants or animals performed by any of the authors.

RESULTS

Figure 1 depicts the front side of the final prototype. The measuring scale ranges from 2 mm (green) through 5 mm (yellow) to 8 mm (red), and the scale is nonlinear because of the nonlinear relationship between the diameter of the stone and the distance marked on the scale. The newly proposed prototype managed to eliminate the material difference between the basket and the spring, which was present in the first prototype [7]. Furthermore, the layout of the scale was improved to make it more comprehensible in comparison with previous scales (Fig. 3).

DISCUSSION

In URS, as in every other surgical procedure, patient safety is the main goal for the surgeon. Despite the many improvements over the years (e.g., invention of ureteral access sheaths, dilatators, safety wires, and especially laser lithotripsy), there is still a need to improve endourological safety, as ureteral injury (of any severity) still occurs in up to 30% of URS cases [11]. Stone diameters greater than 5 mm, a patient history of URS, a dilated proximal ureter, stone location above the ischial spines, and the involvement of a junior urologist are all factors that are known to be associated with a significantly higher incidence of intraoperative complications [10]. The results of our previous study were in line with those of Patel et al. [6] and confirmed that endourologists are able to assess residual stone fragment size accurately enough to make intraoperative decisions about direct extraction or further laser lithotripsy. Conversely, we also showed that it was feasible to measure the stone with the described basket handle scale [8], which could be especially

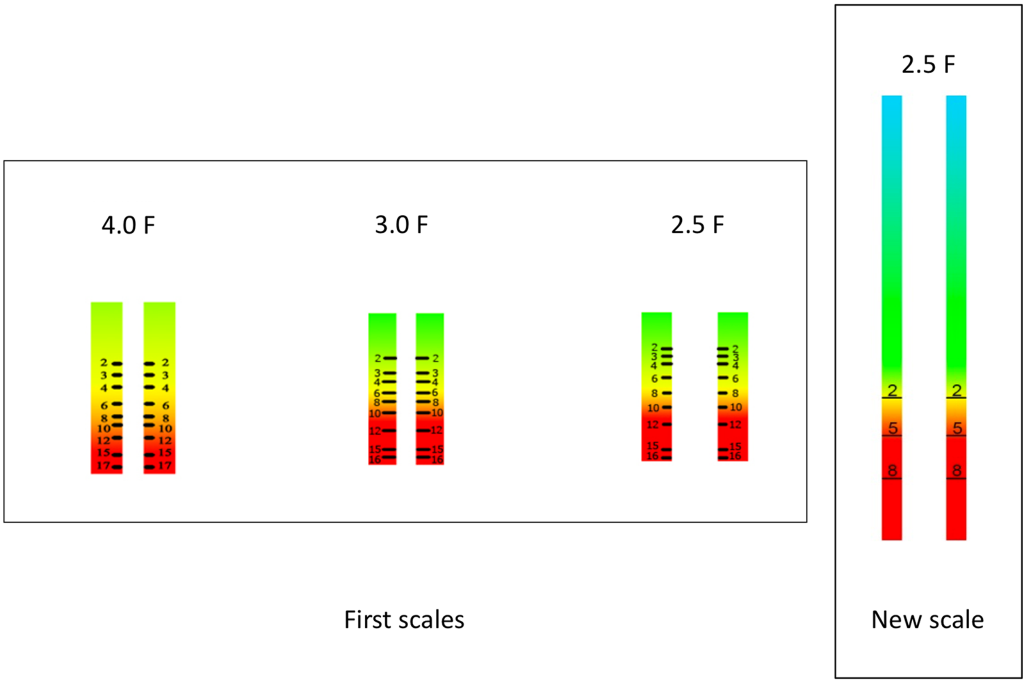

Fig. 3 Evolution of the measuring scale—current nonlinear version ranges from 2 mm (green) through 5 mm (yellow) to 8 mm (red)

suitable for junior endourologists; however, improvements regarding the accuracy of this new method were required and a possible solution is provided in the current study. It has been already shown that the visual stone size estimation is biased by multiple factors, such as the color of the stone and the experience of the surgeon [8]. Interestingly, a slight tendency to underestimate the size of large stones (> 6 mm) was observed [8]; therefore, the measurement of these stone sizes could be enhanced with the proposed basket prototype.

It is already known that intraoperative visual stone assessment and measurements using regular preoperative diagnostic tools (i.e., CT and ultrasound) are biased [12–14]. Other experimental methods such as ultrasound strain sonography have not yet gained clinical application [15]. In our opinion, the modified measuring basket prototype reported here could attempt to level these discrepancies and objectify stone size measurements in the future.

Ludwig et al. recently proposed another approach to improve the intraoperative stone measurement accuracy that was based on additional measuring software calibrated in accordance with the distance of the basket tip in the visual field of the ureteroscope [16]. Future comparison between the "hardware" basket concept and the proposed URS software would be surely interesting to assess their influences on intraoperative outcomes and patients' safety.

CONCLUSIONS

The proposed automatically fixating stone basket with a nitinol spring has the potential to improve the safety and effectiveness of endourological stone retrieval; however, further validation of the proposed prototype regarding measurement accuracy, durability of the device, and patient safety is required.

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Compliance with Ethics Guidelines. This article does not contain any studies with human participants or animals performed by any of the authors.

Data Availability. The manuscript has no associated data.

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